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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,069	11/21/2001	John R. Kane	31976.2000	1481

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EXAMINER

SCHOPFER, KENNETH G

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 03/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,069

Applicant(s)

KANE ET AL.

Examiner

Kenneth G Schopfer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-120 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-120 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, ~~21~~, ~~22~~, ~~24~~, ~~26-28~~, ~~30~~, 45, 46, ~~64-66~~, ~~68-71~~, ~~73~~, 103-105, 111, 113, and 115 rejected under 35 U.S.C. 102(b) as being anticipated by Grahn (USPN 5683438).

3. Referring to claims 1, 2, ~~21~~, ~~22~~, ~~24~~, ~~26-28~~, ~~30~~, 45, 46, ~~64-66~~, ~~68-71~~, ~~73~~, 113, and 115, Grahn teaches all of the limitations of these claims. Grahn teaches a system for raising core body temperature including:

- a) a chamber for enclosing a portion of an extremity including a hollow tubular housing with an entry port;
- b) a pneumatic seal including an annular cuff at the entry port of the chamber to seal the body portion in the chamber inhibiting movement of the portion relative to the chamber;
- c) a thermal energy exchange system associated with the chamber; and
- d) a vacuum system associated with the chamber to generate a sub-atmospheric pressure within the chamber.

Further, the thermal energy exchange system includes a heating energy element that can maintain a temperature between 5°C to 48°C; a flexible membrane that is adapted to envelop the body portion; a backing layer of insulating material that is contiguous with the energy element and

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contacts the flexible membrane; a circulation pump; a fluid reservoir; and a temperature regulator. Referring to figure 1 of Grahn, the chamber surrounds arm 62; the entry port and seal include parts 20 and 26; the heating blanket 34 includes the flexible membrane and the backing layer of insulating material; the thermal energy exchange system includes 46, 44 and 30; and the vacuum system includes 26, 32, and 28.

4. Referring to claims 103-105 and 111, Grahn teaches all of the limitations of these claims as described above. The use of the device of Grahn as described above teaches a method of manipulating core body temperature including the steps of enclosing a body portion in a chamber, sealing the chamber with a pneumatic seal to inhibit movement of the portion relative the chamber, generating a sub-atmospheric pressure within the chamber, exposing the body portion to an energy element assembly, and optimizing contact of the energy element with the body portion via a flexible membrane assembly.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims ~~25, 29, 31-33, 72, 74-78, 93-95, 97-102, 108, 109, and 112~~ ^{94 101/102} are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahn (USPN 5683438).

7. Referring to claims ~~25, 77, 78, 93, 94, 95, 97, 98, 99, and 112~~, Grahn teaches all of the limitations of these claims as described above except for the use of a cooling element in the energy element. It would have been obvious to one of ordinary skill in the art at the time of

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invention that the device of Grahn could be modified to include a cooling element in the thermal exchange system in order to provide for the cooling of hyperthermia patients in addition to the warming of hypothermia patients.

8. Referring to claims ~~29~~ and ~~72~~, Grahn teaches all of the limitations of these claims as described above except for the use of a phase change material for the insulating material of the backing layer. It would have been obvious to one of ordinary skill in the art at the time of invention that a phase change material could have been used in the backing layer of the device of Grahn to ensure that the heat from the energy element was dissipated evenly across the device.

9. Referring to claims ~~31~~, ~~74~~, and ~~100~~, Grahn teaches all of the limitations of these claims as described above except for the use of a perfusion pad in the thermal energy exchange system. It would have been obvious to one of ordinary skill in the art at the time of invention to include a perfusion pad in the energy exchange system of Grahn in order to ensure even distribution of the energy to the treated body portion.

10. Referring to claims 32, 33, 75, 76, 101, 102, 108, and 109, Grahn teaches all of the limitations of these claims as described above except for the sub-atmospheric pressure being between -10 mmHg to -400mmHg. Grahn teaches a negative pressure preferably between -20mmHg to -80 mmHg. It would have been obvious to one of ordinary skill in the art at the time of invention that the vacuum system of Grahn could be constructed to provide negative pressure between -10 mmHg and -400 mmHg as a suitable pressure range to ensure effective heat transfer within the chamber.

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11. Claims ~~3~~⁴-7, 10-20, 34-42, 47-51, 54-63, 107, 110, ~~114~~⁴¹, and 116-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahn (USPN 5683438) in view of Grahn et al.

(USPAP 2002/0019653).

12. Referring to claims ~~3-5~~⁴, 40, ~~41~~⁴, 47-49, 107, and 116-120, Grahn teaches all of the limitations of these claims as described above except for the specific construction of the chamber. Grahn et al. teach a similar device that includes heating or cooling elements where the chamber includes a base member 114, a moveable member 112, and fasteners 120. It would have been obvious to one of ordinary skill in the art at the time of invention to construct the chamber of Grahn with a base and movable portion as in Grahn et al. in order to ensure easier sterilization of the device between uses.

13. Referring to claims 6, 7, 10-20, 42, 50, 51, and 54-63, the combined device of Grahn and Grahn et al. teaches all of the limitations of these claims as described above except for the base and movable member each being associated with a separate flexible membrane, a separate cuff portion, and a separate energy element. It would have been obvious to one of ordinary skill in the art at the time of invention that if the chamber of Grahn were constructed with a base and a moveable member as in Grahn et al. both the base and moveable member could each include a flexible membrane, a cuff, and an energy element to ensure effective thermal transfer to the patient.

14. Referring to claims 34, 35, 38, and 110, the combined device of Grahn and Grahn et al. teaches all of the limitations of these claims as described above. Further, Grahn et al. teach that an insulating device such as a glove or sock may be worn prior to placement of the body portion in the chamber.

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15. Referring to claim 36, the combined device of Grahn and Grahn et al. teaches all of the limitations of this claim as described above except for a layer of the sleeve being transparent. It would have been obvious to one of ordinary skill in the art at the time of invention that the use of a transparent sleeve as in the claims represents an unpatentable design choice over the sleeve of the combined device that would not change the functionality of the device.

16. Referring to claim 37, the combined device of Grahn and Grahn et al. teaches all of the limitations of this claim as described above except for a layer of the sleeve containing a silver compound. It would have been obvious to one of ordinary skill in the art at the time of invention that the sleeve of the combined device could have included a metallic compound such as a silver compound to enhance the energy transfer of the device.

17. Referring to claim 39, the combined device of Grahn and Grahn et al. teaches all of the limitations of this claim as described above except for the insulating material of the sleeve being a phase change material. It would have been obvious to one of ordinary skill in the art at the time of invention to include a phase change material as the insulating material in the combined device to ensure an even temperature distribution across the sleeve.

18. Claims ^{80, 81, 82}~~79~~ 83, and 86-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahn (USPN 5683438) as applied to claim 77 above, and further in view of Grahn et al. (USPAP 2002/0019653).

19. Referring to claims ⁸⁰~~79-81~~, Grahn teaches all of the limitations of these claims as described above except for the specific construction of the chamber. Grahn et al. teach a similar device that includes heating or cooling elements where the chamber includes a base member 114, a moveable member 112, and fasteners 120. It would have been obvious to one of ordinary skill

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in the art at the time of invention to construct the chamber of Grahm with a base and movable portion as in Grahm et al. in order to ensure easier sterilization of the device between uses.

20. Referring to claims 82, 83, and 86-92, the combined device of Grahm and Grahm et al. teaches all of the limitations of these claims as described above except for the base and movable member each being associated with a separate flexible membrane, a separate cuff portion, and a separate energy element. It would have been obvious to one of ordinary skill in the art at the time of invention that if the chamber of Grahm were constructed with a base and a moveable member as in Grahm et al. both the base and moveable member could each include a flexible membrane, a cuff, and an energy element to ensure effective thermal transfer to the patient.

21. Claims ~~23, 67~~ and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahm (USPN 5683438) in view of Cho et al. (USPN 5369807).

22. Referring to claims 23, 67, and 106, Grahm teaches all of the limitations of these claims as described above except for the seal containing a bladder. Cho et al. disclose a similar device where air bladders are used to create a pneumatic seal in a chamber containing a user's hand. It would have been obvious to one of ordinary skill in the art at the time of invention to use a bladder seal as in Cho et al. in the device of Grahm as an effective means to seal a body portion inside the chamber.

23. Claim ~~96~~ is rejected under 35 U.S.C. 103(a) as being unpatentable over Grahm (USPN 5683438) as applied to claim 95 above, and further in view of Cho et al. (USPN 5369807).

24. Referring to claim ~~96~~, Grahm teaches all of the limitations of this claim as described above except for the seal containing a bladder. Cho et al. disclose a similar device where air bladders are used to create a pneumatic seal in a chamber containing a user's hand. It would have

been obvious to one of ordinary skill in the art at the time of invention to use a bladder seal as in Cho et al. in the device of Grahm as an effective means to seal a body portion inside the chamber.

25. Claims 8, 9, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahm (USPN 5683438) in view of Grahm et al. (USPAP 2002/0019653) as applied to claims 7 and 51 above, and further in view of Cho et al. (USPN 5369807).

26. Referring to claim 8, 9, 52, and 53, Grahm and Grahm et al. teach all of the limitations of these claims as described above except for the seal containing a bladder. Cho et al. disclose a similar device where air bladders are used to create a pneumatic seal in a chamber containing a users hand. It would have been obvious to one of ordinary skill in the art at the time of invention to use a bladder seal as in Cho et al. in the combined device of Grahm and Grahm et al. as an effective means to seal a body portion inside the chamber.

27. Claims 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahm (USPN 5683438) as applied to claim 77 above, and further in view of Grahm et al. (USPAP 2002/0019653) as applied to claim 83 above, and further in view of Cho et al. (USPN 5369807).

28. Referring to claim 84 and 85, Grahm and Grahm et al. teach all of the limitations of these claims as described above except for the seal containing a bladder. Cho et al. disclose a similar device where air bladders are used to create a pneumatic seal in a chamber containing a users hand. It would have been obvious to one of ordinary skill in the art at the time of invention to use a bladder seal as in Cho et al. in the combined device of Grahm and Grahm et al. as an effective means to seal a body portion inside the chamber.

29. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grahn (USPN 5683438) in view of Grahn et al. (USPAP 2002/0019653) as applied to claim 42 above, and further in view of Borders (USPN 6149674).

30. Referring to claim 43, the combined device of Grahn and Grahn et al. teaches all of the limitations of this claim as described above except for the third and fourth cuffs at the distal end of the chamber. Borders teaches a similar device that includes cuffs at the proximal and distal end of a chamber so that a portion of an extremity can be enclosed without the distal end of the extremity being enclosed within the chamber. It would have been obvious to one of ordinary skill in the art at the time of invention to include cuffs at the distal end of the chamber of Grahn and Grahn et al. as in Borders in order to provide thermal energy to a portion of an extremity not including the distal end of the extremity.

31. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grahn (USPN 5683438) in view of Grahn et al. (USPAP 2002/0019653) as applied to claim 42 above, and further in view of Borders (USPN 6149674) as applied to claim 43 above, and still further in view of Cho et al. (USPN 5369807).

32. Referring to claim 44, the combined device of Grahn, Grahn et al., and Borders teaches all of the limitations of this claim as described above except for each cuff containing a bladder. Cho et al. disclose a similar device where air bladders are used to create a pneumatic seal in a chamber containing a users hand. It would have been obvious to one of ordinary skill in the art at the time of invention to use a bladder seal as in Cho et al. in the combined device of as an effective means to seal a body portion inside the chamber.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth G Schopfer whose telephone number is 703-305-2649. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

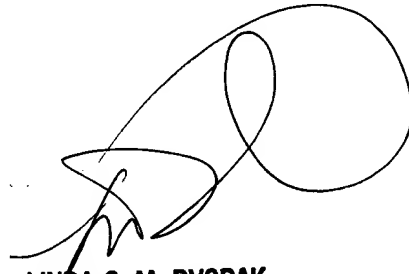
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 703-308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and, 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



KS

March 24, 2003



LINDA C. M. DVORAK
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